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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,501	06/15/2006	Vamsi Krishna Mootha	WIBL-P01-013	3194

28120 7590 08/05/2009
ROPES & GRAY LLP
PATENT DOCKETING 39/41
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

HAMA, JOANNE

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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08/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,501	Applicant(s) MOOTHA ET AL.	
	Examiner JOANNE HAMA	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,17,19,20,35,42,47,78,93 and 106-126 is/are pending in the application.
- 4a) Of the above claim(s) 1,17,19,20,35,42,47,78,113 and 114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 93,106-112 and 115-126 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant filed a response to the Non-Final Action of September 9, 2008 on December 11, 2008 and April 23, 2009.

Claims 1, 17, 19, 20, 35, 42, 47, 78, 113-117 are withdrawn. Claims 17, 42, 47, 78, 93, 10-110, 112, 115 are amended. Claims 2-16, 18, 21-34, 36-41, 43-46, 48-77, 79-92, 94-105 are cancelled. Claims 118-126 are new.

With regard to the restriction of claims 113, 114, Applicant indicates that claims 113, 114 require each step of claim 93 and fall within the scope of claim 93. As such, claims 113, 114 should be included in the examination (Applicant's response, page 9-10). In response, to clarify, the relationship of claims 113, 114 to claim 93 is not a restriction, but each claim is a species of claim 93. Had claims 113 and 114 been presented at the time the restriction was written (September 6, 2007), a species restriction between a method of screening for compounds that change expression of two OXPHOS-CR gene (claim 93), a method of screening for compounds that change expression of two OXPHOS-CR gene and further identifying the effect of the agent of mitochondrial number or mitochondrial function (claim 113), a method of screening for compounds that change expression of two OXPHOS-CR gene and further assessing whether the agent increase a desired biological response (claim 114) would have been required. The claims are distinct from each other because the method of identifying compounds that affect mitochondrial number or mitochondrial function (claim 113) and a method of assessing if a compound increases a desired biological response (claim 114) require distinct steps from those of claim 93. Applicant is reminded that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to

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additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

With regard to claims 115-117, the claims have been amended to recite a species of claim 93. As such, claims 115-117 are not withdrawn and are pending and Applicant's amendment prompts a species election. It is noted that Applicant has also added new claims (claims 118-126) which also prompts a species election. Applicants have amended the pending claims and added new claims that are drawn to a number of distinct species that were not presented before the first Office action on the merit. See MPEP 818.02(b) Generic Claims Only — No Election of Species:

"Where only generic claims are first presented and prosecuted in an application in which no election of a single invention has been made, and applicant later presents species claims to more than one >patentably distinct< species of the invention, **>the examiner may require applicant to elect< a single species. The practice of requiring election of species in cases with only generic claims of the unduly extensive and burdensome search type is set forth in MPEP § 808.01(a)."

Claims 93, 106-112, 115-126 are pending.

This application contains claims directed to the following patentably distinct species:

Claim 93 is drawn to the method being performed 1) in vivo, and 2) in vitro followed by in vivo (see claim 115), and one must be elected. Should Applicant elect that the method is performed in vitro and is followed by being performed in vivo, a further species election on the organism in which the method is performed (see claims 116-117) is required.

Claim 93 is drawn to a test cell being mammalian (see claims 93, 118) or non-mammalian (e.g. yeast) and either mammalian or non-mammalian must be elected.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently,

claims 93, 106-112, 118, 119, 121, 124-126 are generic for the method being performed in vivo and in vitro, followed by a step in vivo.

claims 93, 106-112, 112-125 are generic for the cell type (i.e., mammalian or non-mammalian).

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a

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claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

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/Joanne Hama/
Primary Examiner
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